

ICH M2 Recommendations
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General - Recommendation 1.1

29APR1996

Title: General 1.1 - Procedure for Recommendations

Date: 29 April 1996

Background:

Given the purpose of ICH, the Expert Working Group (EWG) of ICH M2 (ESTRI) has decided that the outcome of their activities should result in recommendations to be adopted by the ICH Steering Committee. Due to the information technology (IT) nature of the topic, the activities of the EWG will result in recommendations which will be subject to change as both science and technologies change. Therefore, it is proposed that the M2 recommendations be approved and distributed within the three regions in a manner which will facilitate periodic updates. This is in contrast to the Safety, Efficacy, and Quality topics whose recommendations are essentially one-time products which will be incorporated into regulations, guidelines, or other administrative measures in all three regions.

Recommendation:

The M2 EWG proposes that the following procedure relating to recommendations made to the ICH Steering Committee be adopted by the Steering Committee:

The recommendation:

- is written according to the attached template
- is numbered according to the major categories

1. General
2. Physical Media
3. Network
4. Security
5. Format

(Note: Other categories will be identified and added as needed)

- is given a running number within the categories, e.g., Recommendation 2.1 for the first recommendation in the category 2 Physical Media
- is an agreed product from the entire EWG
- is presented (in person or writing) to the Steering Committee for approval and sign off
- is implemented by coordinating among the Regulatory Authorities to ensure compatibility
- is published in a guidance manual developed by the EWG, including specific processes to be used for implementing recommended standards in all three regions

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Conditions:

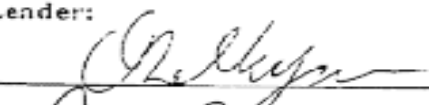

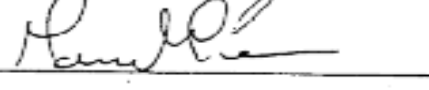


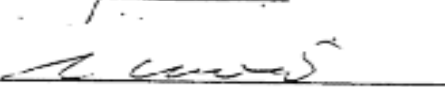
- each recommendation will be written using the attached template
- header contains current date of recommendation which has to be updated with each version
- footer contains version number (to be updated with each revision) and page number
- assignment of recommendation number has to be handled centrally by the EWG

Remarks:

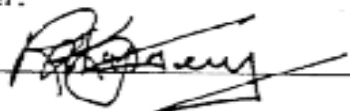
None

SIGNATURES

Topic Leaders:

<EU> 	<EFPIA> 
<FDA> 	<PhRMA> 
<MHF> 	<JPMA> 

Observer:

<HPB> 

Attachment - Recommendation Template

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EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
"title" - Recommendation # **DDMMYYYY**

Title:

Date:

Background:

Recommendation:

Conditions:

Remarks:

SIGNATURES

Topic Leader:

<EU>_____ <EFPIA>_____

<FDA>_____ <PhRMA>_____

<MHW>_____ <JPMA>_____

Observer:

<HPB>_____

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